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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09-48]

East Main Street Pharmacy; Affirmance of Suspension Order

On April 23, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to East Main Street Pharmacy ("Respondent"), of Columbus, Ohio. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BE5902615, as a retail pharmacy, as well as the denial of any pending applications to renew or modify its registration, "for reason that [Respondent's] continued registration is inconsistent with the public interest, as that term is used in **21 U.S.C. 823(f)** and **824(a)(4)**." ALJ Ex. 1, at 1. More specifically, the Order alleged that Respondent had violated its corresponding responsibility under Federal regulations to not fill unlawful prescriptions. Id. at 2 (citing **21 CFR 1306.04(a)**).

The Show Cause Order alleged that Respondent was owned by Eugene H. Fletcher, Respondent's sole pharmacist, and that from "September 2005 through February 2006" it "filled 6,619 controlled substance prescriptions" including 4,979 prescriptions issued by Dr. Paul Volkman of Portsmouth, Ohio. Id. at 1. The Show Cause Order further alleged that on February 10, 2006, DEA had immediately suspended Volkman's registration and that the Agency subsequently found that he had "repeatedly violated Federal law by prescribing controlled substances without a legitimate medical purpose and outside the course of professional practice." Id. (citing Paul H. Volkman, 73 FR 30630, 30642 (2008)). The Order also alleged that "Dr. Volkman directed his patients to have their prescriptions filled at [Respondent, who] filled them mostly in exchange for cash," and that "[n]inety-eight percent of Dr. Volkman's patients that filled their prescriptions at [Respondent] did not reside in the Columbus area." Id. Relatedly, the Order alleged that some of Volkman's patients travelled from Portsmouth and Chillicothe, Ohio to Respondent, a distance of 92 and 45 miles, respectively; that one of Volkman's patients had travelled from South Central Kentucky to Respondent to obtain his prescriptions, that many of Volkman's patients were obtaining prescriptions from other physicians, and that several of these persons died of overdoses. Id. at 2.

The Show Cause Order further alleged that Respondent "filled prescriptions for combinations of controlled substances and the non- controlled, but highly addictive drug carisoprodol [sic] (Soma), under circumstances indicating that the prescriptions were issued outside the usual course of professional practice." Id. at 2. More specifically, the Order alleged that Respondent filled for numerous patients of Volkman, "large quantity prescriptions" for a benzodiazepine, two narcotic pain medications, and Soma, and that "[t]hese drug combinations are generally known in the medical and pharmacy profession as being favored by drug-seeking individuals." Id. The Order also alleged that Respondent "filled several of the above combination prescriptions when the patients should have had two to three weeks' supply of medication from a previous prescription" and it either "did not recognize, or ignored these indicators of drug diversion and abuse." Id.

Finally, the Order alleged that, with regard to Dr. Volkman's prescriptions, Mr. Fletcher had told a DEA Investigator "that it was 'not [his] job to question a physician.'" Id. Based on the above, the Order alleged that Respondent "knew, or should have known that [the] controlled substance prescriptions it filled for patients of Dr. Volkman were for no legitimate medical purpose." Id.

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[REDACTED]

[REDACTED]

[REDACTED]

Pursuant to my authority under **21 U.S.C. 824(d)**, on November 10, 2009, I further ordered that Respondent's registration be suspended immediately because its "continued registration * * * constitutes an imminent danger to the public health and safety." ALJ Ex. 8, at 1. The Immediate Suspension Order incorporated by reference the allegations of the Order to Show Cause and cited the additional allegations that Respondent had recently filled more prescriptions for controlled substances for two persons who were travelling substantial distances to obtain the drugs. Id. at 1-2.

More specifically, the Immediate Suspension Order alleged that on October 2, 2009, L.D.C., a resident of Portsmouth, Ohio obtained from a physician practicing in Wheelersburg, Ohio, prescriptions for 90 tablets of oxycodone 30 mg. and 60 tablets of carisoprodol (a non- controlled but highly abused drug which metabolizes into meprobamate, a Schedule IV depressant), and that she then travelled "approximately 100 miles from Wheelersburg to Columbus" and filled the prescriptions at Respondent. Id. at 2. The Order alleged that the next morning, L.D.C. [REDACTED]

The Immediate Suspension Order also alleged that on various dates including July 3, September 1, and October 1, 2009, Respondent had filled various prescriptions for oxycodone issued to S.J.P., of Waverly, Ohio. Id. The Order alleged that Waverly, Ohio is "approximately 64 miles from Columbus" and that the prescriptions were issued by physicians who practiced "in Lees [sic] Summit, Missouri," as well as in Dayton and Portsmouth, Ohio, which are 78 and 92 miles, respectively, from Respondent. Id.

The Order thus alleged that Respondent "knew or should have known that the above dispensed controlled substances were likely to be diverted or used for other than legitimate medical purposes" and that "[b]y dispensing such prescriptions, [Respondent] failed to fulfill its corresponding responsibility for the proper dispensing of controlled substances." Id. at 3. Based on the above, I concluded that there was a "substantial likelihood that [Respondent] will continue to violate its corresponding responsibility to properly dispense controlled substances" and that Respondent's continued registration during the pendency of the proceeding "would constitute an imminent danger to the public health and safety." Id. I, therefore, ordered that Respondent's registration be suspended.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

On May 18, 2010, the ALJ issued her Recommended Decision. Applying the public interest factors, see **21 U.S.C. 823(f)**, the ALJ concluded that the "record demonstrates that it is against the public interest for the Respondent to retain its controlled substances registration" and recommended that "Respondent's registration be revoked and any pending applications for renewal be denied." ALJ at 54.

Under the first factor--the recommendation of the appropriate State licensing board or professional disciplinary authority--the ALJ found that "the Ohio Board of Pharmacy has not made a recommendation in this proceeding." Id. at 45. The ALJ further found, however, that on March 5, 2009, the Board had fined Mr. Fletcher and placed his license on probation because he "did not ensure, on three separate occasions, that a qualified person was at * * * Respondent to receive deliveries of controlled substances," which "were left at unsecure locations pending his arrival at the Respondent." Id. The ALJ concluded that this "security violation weighs in favor of revocation" of Respondent's registration. Id.

As to the second factor--Respondent's experience in dispensing controlled substances--the ALJ found that "Respondent ignored numerous 'red flags' when dispensing controlled substances to Dr. Volkman's patients." Id. at 46. In particular, the ALJ relied on the testimony and report of the Government's Expert that various patients of Volkman:

- (1) were driving long distances to have their prescriptions filled,
- (2) were receiving large volumes of controlled substances in the highest strength in each prescription,
- (3) were not receiving individualized therapy, for 75% of these patients received the same four drug 'cocktail,'
- (4) were paying large amounts of cash for their prescriptions, and (5) were receiving multiple narcotic pain killers on the same day.

Id.

Noting Agency precedent that "[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescriptions," id. at 47 (quoting Ralph J. Bertolino, 55 FR 4729, 4730 (1990)), the ALJ concluded that Respondent "clos[ed] a blind eye to these obvious red flags," and accordingly, "was not taking seriously its corresponding responsibility for these prescriptions" to

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these patients. Id. (citing **21 CFR 1306.04(a)**).

The ALJ also noted that "[m]any of Dr. Volkman's patients had told [Respondent's owner] that other pharmacies would not fill Dr. Volkman's prescriptions" and yet Respondent's owner did not call these other pharmacies to ask why. Id. She also noted that Respondent had an "unconventional" relationship with Volkman in that Volkman referred his patients to Respondent, that Mr. Fletcher and Volkman's office would coordinate keeping Respondent "open late in the evenings" so that Volkman's patients could fill their controlled substance prescriptions, and that it "kept large quantities of controlled substances on hand to fill these large